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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,144	08/27/2008	Lionel Christopher Bainbridge	IPLTP0107US	1558
23908 7590 06/02/2011 RENNER OTTO BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE NINETEENTH FLOOR CLEVELAND, OH 44115			EXAMINER	
			CHAPMAN, GINGER T	
			ART UNIT	PAPER NUMBER
			3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Summary	10/598,144	BAINBRIDGE, LIONEL CHRISTOPHER			
omec Action Cammary	Examiner	Art Unit			
	Ginger T. Chapman	3761			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 18 Au	ugust 2006.				
·—	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.			
Disposition of Claims					
 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrav 5) Claim(s) is/are allowed. 6) Claim(s) 1-14 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or 	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on 18 August 2006 is/are: Applicant may not request that any objection to the orange Replacement drawing sheet(s) including the correction of the orange of the second sec	a) accepted or b) objected the drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	4)	ate			
Paper No(s)/Mail Date <u>08/18/2006; 12/31/2008</u> . 6) Other:					

DETAILED ACTION

Status of the Claims

Claims 1-14 are pending in the application having a filing date of 27 August 2008; claims 15-22 are previously canceled by way of preliminary amendment.

Priority

This application is a national phase of International Application No.

PCT/GB2005/000561 filed February 17, 2005 and published in the English language;

Transmittal Letter for entry into the national stage in the United States filed August 18, 2006;

Application Data Sheet 37 CFR 1.76 priority claimed to Application No. GB 0403648.9 filed

February 18, 2004 as required by 35 USC 119(b), 37 CFR 1.55(a). The Petition Decision issued

February 25, 2009 grants Applications' Petition filed August 27, 2008, holding the application not abandoned, accordingly for purposes of examination acknowledgement is made of

Applicants' claim for priority under 35 USC 119(a)-(d).

Claim language interpretation

Given the broadest reasonable interpretation of the claim consistent with the Specification as it would be interpreted by one of ordinary skill in the art, the claim limitation "limb-sealing means" is not considered to invoke 35 USC 112, 6th paragraph because: "limb-sealing" is considered a structural term rather than functional language that modifies the "means" phrase; the limitation includes the structure necessary to perform the claimed function because the means must be able to achieve a seal that is "located close to or at a respective end of" a sleeve" that is sized and shaped to fit a human limb between the limb and the sleeve; the Specification provides descriptions of the claim term that are sufficient to inform one of ordinary

skill in the art that the term denotes structure, and there is evidence in the prior art that the claim term has art-recognized structure to perform the claimed function, see e.g. by way of evidence, US 3,968,792; 4,991,593; 5,5,592,953 and as further detailed below in the analysis of the claims on the merits.

Therefore for purposes of examination, the claim is interpreted as not invoking 35 USC 112, 6th paragraph and thus not limited to the specific structure disclosed in the Specification for achieving that function, although limitations from the Specification will not be imported into the claims from the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 6, 8-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (WO 03/090598) in view of Delao (US 5,592,953).

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With respect to claim 1, Rosenberg discloses a device (Figure 1; page 14, line 5) adapted to assist the sterilization of a limb surface (page 1, lines 5-8; page 4, lines 1-5; page 7, lines 24-25 and lines 29-31; page 11, lines 23-25), and comprising:

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a flexible tubular sleeve 3, closed at one end (page 10, lines 11-13; page 14, lines 5-6 and lines 11-12), shaped and sized so as to loosely fit, in use, around the limb of a patient whose limb surface is to be sterilized (page 7, lines 31-34; page 14, lines 21-25); and

limb-sealing means 4 located close to ar at a respective end of said sleeve, capable of forming, in use, a seal between the sleeve 3 and the limb of a patient (figure 1; page 14, lines 11-17).

Rosenberg discloses the claimed invention except for respective limb-sealing means. Rosenberg, at page 14, lines 11-19, provides motivation for the open end of the sleeve into which the limb is inserted will be sealable by sealing means which can be retained sufficiently close to the surface of the limb to prevent leakage of aqueous treatment and sterile solutions from within the sleeve. Thus Rosenberg provides motivation for the open end of the sleeve to have limb-sealing means. The instant Specification, at page 7, lines 15-17, Figures 8-12, indicates that the instant closed end is intended to be opened in use to form a second open end opposite the first open end to be pulled over a limb of a patient. The sealing means of Rosenberg are disclosed in the instant Specification at page 5, lines 24-25; page 9, line 31 as suitable embodiments of the instant claimed limb-sealing means and thus are capable of forming a seal between the sleeve and limb of a patient at an open end of the sleeve in the substantially identical manner. Thus one of ordinary skill in the art at the time the invention was made would expect the seal at the open end of the sleeve of Rosenberg to be capable of forming a seal at an open other end of the sleeve.

The examiner notes that multiples of the same structure do not lend additional patentable weight and is an obvious modification.

Delao, at column 2, lines 40-46, provides motivation for a sleeve having respective limb-sealing means, each located close to or at a respective end of the sleeve to form seals thereabouts to prevent leakage of aqueous treatment solutions from or to within the sleeve, i.e. sealing in or out fluids, at respective ends of said sleeve in use conditions such as pre-operative sterilization of a limb site (column 5, lines 5-7) when both ends of the sleeve are open for slipping over the limb to be treated then subsequently sealed to administer the treatment. As best depicted in Figures 1-3, Delao teaches respective limb-sealing means 12, 14 located close to or at a respective end of said sleeve (column 6, lines 20-30); said limb-sealing means disclosed by Rosenberg and the instant Specification at Figure 1 (6), Figures 5-6 (17) as suitable embodiments of the instant claimed limb sealing means.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the limb-sealing means located close to or at at the open end of the sleeve of Rosenberg at respective ends of the sleeve as taught by Delao since Rosenberg states, at page 14, lines 27-31; page 21, line 12 to page 22, line 5, that one of ordinary skill in the art could readily devise many modifications and variations without departing from the scope thereof by applying current knowledge to readily modify and adapt the means foDelao states, at column 2, lines 32-35; column 4, lines 6-12; column 6, lines 50-53, that a plurality of such limb-sealing means can be located laterally spaced about the circumference of the sleeve to fit over /accommodate a broad range of different sized limbs /appendages as well as permitting different positioning of the sleeve upon the appendage, thereby providing a more versatile device.

With respect to claim 4, Rosenberg discloses wherein the limb-sealing means are so constructed as to create a wiping actions when slid, in use, along a patient's limb (page 14, lines 11-19, disclosing the sealing means is retained sufficiently close to the skin, and comprises the same structure as the instant claimed limb sealing means (see claim 1, *supra* for detailed analysis of this limitation), and thus will likewise perform the claimed wiping action in use when slid along a patient's limb).

With respect to claim 6, Rosenberg discloses wherein the sleeve is substantially transparent (page 13, lines 8-11).

With respect to claim 8, Rosenberg discloses at least one tab or loop 4 to assist pulling the sleeve, in use, along a patient's limb (Figure 1; disclosing the means 4 can be a drawstring, disclosed in the instant Specification at page 5, lines 10-12; page 10, lines 25-26, as a suitable embodiment of the instant claimed loops and are located in the substantially identical location and thus would perform the claimed function of assisting pulling said sleeve along a patient's limb).

With respect to claim 9, Rosenberg discloses the claimed invention except for fastening means to hold the two ends of the sleeve close to each other, whilst the sleeve is positioned on a patient's limb. Rosenberg discloses fastening means to hold the sleeve in position on a patient's limb, thus providing motivation for such (page 14, lines 13-25). Delao, at column 4, lines 6-15, provides motivation for a sleeve that can be positioned in a variety of locations or sites along a patient's appendage / limb and along a portion of said limb. Delao, at column 5, lines 28-29 and lines 37-41, lines 49-50, lines 58-62, teaches the length of the sleeve can be adjusted i.e. the ends of the sleeve can be moved close to each other or farther apart from each other to thereby adjust

the sleeve length at a desired location or site along a patient's limb. Delao teaches fastening means 10 that holds the two ends of the sleeve 1, 3 close to each other any desired locations at various sites located along a limb, whilst the sleeve is positioned on a patient's limb (column 3, lines 15-25. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the fastening means of Rosenberg to hold the ends of the sleeve close to each other as taught by Delao since Delao states, at column 6, lines 50-53, that the benefit of forming the sleeve with this design is that it effectively accommodates different size appendages as well as permitting different positioning of the sleeve along the patient's appendage/ limb.

With respect to claim 13, Rosenberg discloses wherein at least one of the limb sealing means adapts to fit limbs of different circumferences without the need to cut section from the device (page 14, lines 15-25).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Delao and further in view of Reyes (US 5,494,050).

With respect to claim 2, the combination of Rosenberg and Delao discloses the claimed invention except for wherein at least one of the limb-sealing means comprises a perforated elastic diaphragm. Rosenberg and Delao disclose the limb-sealing means comprises a perforated elastic member, thus providing motivation for such.

It is noted that claim 2 recites a "perforated elastic diaphragm" while claim 7 recites "sleeve is perforated"; the claim 2 "perforated" structure is "a hole" in an elastic sheet sized, dimensioned and adapted to fit over a limb and slide along said limb while the claim 7 "perforated" structure is an area "weakened, by perforation", as best depicted and discussed in

the instant Specification with reference to Figures 2-3 reference character (8); Figures 5, 7 reference character (16); page 10, lines 4-10 and lines 24-26. Thus the instant claim 2 perforated is considered to comprise a hole.

Rosenberg discloses at least one of the limb-sealing means 4 comprises an elastic band near an open end of the sleeve into which the limb is inserted by sealing means fitting close to the surface of the limb to prevent leakage of aqueous solutions from within the sleeve, said sealing means near to the open end of the sleeve (Figure 1; page 14, lines 11-17), thus providing motivation for an elastic band. Delao teaches at least one of the limb-sealing means comprises an elastic band 10, 12, 14 located close to or at respective open ends of said sleeve (Figure 3; column 5, lines 7-9, lines 33-35 and line 58) thus providing motivation for such.

Both the elastic bands of Rosenberg and Delao are "perforated" in the sense that both seals provide a circumferential hole which is adapted, sized and dimensioned for a limb to fit therethrough, and thus perform the same function as the instant claimed perforated elastic diaphragm of forming a seal between the sleeve and the limb of a patient, wherein the only difference would be the width dimension of the elastic member.

Reyes, at column 2, lines 10-12, lines 27-29 and lines 36-42, provides motivation for limb-sealing means suitable for use with surgical procedures, that are economical and easy to use on irregularly-shaped areas of the body, in particular arm and leg limbs, to minimize the possibility of fluid leaks thereabout thereby reducing spread of infections. As best depicted in Figures 1-4, 7, 12, 13 at (30, 32, 34), Reyes teaches a perforated elastic diaphragm (column 5, lines 1-12), discussed and depicted in the instant Specification at Figures 2-3 at (7, 8, 11), Figures 14a-b at (42, 48); page 10, lines 4-10; page 12, lines 29-33, as a suitable embodiment of

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the instant claims perforated elastic diaphragm. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the limb-sealing means of Rosenberg and Delao as perforated elastic diaphragm as taught by Reyes since Reyes states, at column 5, lines 5-12, that the benefit of forming the limb-sealing means with this design is that it conforms to the shape of the body member / limb that passes through the hole and the elastic material of the seal, of which Rosenberg and Delao are also comprised, rests directly on the body member to be supported when forming the seal between sleeve and limb.

Claims 3, 11-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Delao and further in view of Polyakov et al (US 5,437,602).

With respect to claim 3, the combination of Rosenberg and Delao discloses the claimed invention except for wherein at least one of the limb-sealing means comprises a substantially frusto-conical portion. Rosenberg provides motivation for limb-sealing means that is sufficiently elastic, pliant and flexible to form a seal around a limb without causing friction, abrasion, or trauma (page 7, lines 31-34; page 10, lines 15-16). Delao provides motivation for limb-sealing means that provides a uniform snug seal while preventing a tourniquet effect (column 2, line 45; column 4, lines 64-65). Polyakov provides motivation for limb-sealing means that does not have a tourniquet effect to prevent compression damage to the limb, (column 1, lines 13-22 and lines 48-51). As best depicted in Figures 9-10 (53), 11 (50a), Polyakov teaches providing limb-sealing means comprising frusto-conical portions 50(a), 53 in order to and provide a tapered leg portion that can accommodate most patients' leg lengths and diameters while preventing a tourniquet effect (column 3, lines 57-59; column 4, lines 19-25, lines 31-32 and lines 64-68 to column 5, lines 1-2.).

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Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the limb-sealing means of Rosenberg and Delao with a frustoconical portion as taught b Polyakov since Polyakov states, at column 2, lines 23-28, that the benefit of forming a portion with this design is that it can accommodate various limb diameters and prevents a tourniquet effect thereby preventing further damage to an injured site.

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With respect to claims 11 and 14, the combination of Rosenberg and Delao discloses the claimed invention except for a valve arrangement to allow egress of air from within the sleeve whilst the sleeve is positioned on a patient's limb (claim 11); wherein a resealable portal is provided (claim 14). Rosenberg, at page 14, lines 11-17, discloses the sleeve comprises a closed end and a sealable open end, thus, when the sleeve of Rosenberg is slid along the limb, air from within the sleeve can be evacuated from the open end as the sleeve is applied to the limb. Polyakov, at column 1, lines 30-36, provides motivation to prevent air pockets that promote the growth of microbes within the sleeve. As best depicted in Figures 6, 11 and 13, Polyakov teaches a valve arrangement 25-26, 57-58 to allow egress of air from within the sleeve whilst the sleeve is positioned on a patient's limb (column 4, lines 12-19) (claim 11) and a resealable portal 25, 26 is provided (claim 14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sleeve of Rosenberg/ Delao with a valve arrangement and resealable portal as taught by Polyakov since Polyakov states, at column 1, lines 30-36, that the benefit of forming a sleeve with this design is that it prevents air pockets which promote the growth of microbes within the sleeve thereby reducing the risk of infection.

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With respect to claim 12, the combination of Rosenberg and Delao discloses the claimed invention except for a limb-sealing means which is sized and shaped to be extendable beyond an opening formed by removal of the sealed end of the device.

Rosenberg, at page 14, lines 15-25, discloses the sleeve comprises retaining means near an open end of said sleeve and sufficiently adaptable to afford a reasonable volume within the sleeve to serve any individual case. Review of the instant Specification, in particular at Figures 6-7 (11) and page 10, lines 4-10 and lines 28-31, indicates that the sleeve is extendable beyond an opening by means of elastic sheet 7 forming limb sealing means having a frustoconical portion 11 that provides the claimed extension beyond the opening. Polyakov, at column 1, lines 46-50, provides motivation to provide limb-sealing means that does not have a tourniquet effect on the limb or compression that impedes vascular, lymphatic or circulatory flow. As best depicted in Figures 9-10 (53); Figure 11 (50a), Polyakov teaches the substantially identical limbsealing means comprising a frustoconical portion that would also be extendable beyond the opening 34 (column 2, lines 23-24; column 4, lines 23-24). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the limb-sealing means of Rosenberg / Delao sized and shaped to be extendable beyond an opening formed by removal of the sealed device as taught by Polyakov since Polyakov states, at column 4, lines 19-25, lines 31-32 and line 64 to column 5, line 2, that the benefit of forming the limbsealing means with this design is that the frustoconical portion of the limb-sealing means can accommodate different limb sizes and prevents a tourniquet effect when sealed to a patient

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Delao and further in view of Miller et al (US 3,327,705).

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With respect to claim 5, the combination of Rosenberg and Delao discloses the claimed invention except for wherein both ends of the sleeve are initially closed. Rosenberg, at page 13, lines 27-33 and page 5, lines 11-19, lines 24-31, provides motivation to provide the sleeve sealed in a sterile kit in order to retain treatment compounds provided within the sleeve. As best depicted in figure 1 and column 1, lines 41-42 and lines 50-56; column 2, lines 13-20, Miller provides motivation for a sleeve containing medicaments provided in sealed form to retain the sterile medicaments by providing both ends of the sleeve initially closed (column 2, lines 13-19).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Delao and further in view of Olin et al (US 2006/0291755 A1).

With respect to claim 7, the combination of Rosenberg and Delao disclose the claimed invention except for wherein at least one of any sealed end of the sleeve is perforated, nicked, weakened, or otherwise adapted to assist opening of that sealed end. Rosenberg, at page 5, lines 23-19 and lines 30-31, provides motivation for a sleeve in a sterile sealed package to preserve the sterile contents and a sealed end that can be opened to receive a limb. Olin, which is directed to flexible bags or pouches used for waste containment and disposal and is thus reasonably pertinent in the field of endeavour of sealed flexible bags and sleeves and thus is analogous art, at paragraph [0052], provides motivation for a sealed bag that provides a secure closure of the contents and provides an easy way for a consumer to open the bag. As best depicted in Figure 1, Olin discloses a sleeve-shape bag 10 having a sealed end that is perforated, weakened or otherwise adapted 26 to assist opening of that sealed end [0052]. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sealed end of Rosenberg/Delao perforated, nicked, weakened or otherwise adapted to assist

opening of a sealed end since Olin states, at paragraph [0052], that the benefit of forming the bag with this design is that it provides a secure closure of the sealed end during handling and shipping stresses to protect the contents of the bag, and provides an easy way for a consumer to open the bag.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Delao and further in view of Miller et al (US 3,327,705).

With respect to claim 10, the combination of Rosenberg and Delao discloses the claimed invention except for an easily rupturable container inside the sleeve. Rosenberg, at page 5, lines 13-31; page 12, lines 1-3; page 13, line 33 to page 14, line 2, discloses sterilizing agents inside (in use) the sleeve, that can be sealed therein to maintain their sterility during storage until the sleeve is used, thus providing motivation for a sterilizing agent inside the sleeve, but does not disclose the agent inside an easily rupturable container. As best depicted in Figure 1, Miller teaches a sleeve 11, closed at one end to fit around a limb of a patient and with an easily ruptured container 13 of medicinal and treatment agents inside (in use) the sleeve (column 2, lines 8-10, lines 22-33). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sterilizing agent of Rosenberg inside an easily rupturable container as taught by Miller since Miller states, at column 2, lines 26-27, that the benefit of forming the sleeve with this design is that the agent within the container is readily released and circulates over the limb within the sleeve.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

LeVahn (US 4,991,593) Figures 1-2 and 5; Marasco et al (US 6,635,035 B1) Figure 1; Trammel (US 5,029,579) discloses limb-sealing means having a frusto-conical portion 72; Fischer (US 3,744,491) Figures 1 and 5; Small (US 3,968,792)' Warner (US 6,276, 364 B1) Figure 6; Gardner (US 3,186,404) Figure 1; Greco (US 5,312,385) Figure 1-2.

Additional References cited as Category "X" references in International Search Report and UK Search Report made of record by way of Applicants' Information disclosure Statements are acknowledged: DE 20002902U1; NL 8102851; GB 2276323 A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 10:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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